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Amendment
Attorney Docket No. S85.2H-9608-US02

Remarks

This Amendment is in response to the Final Office Action dated August 20, 2004.

It is apparent from the Final Office Action that the claims are not being understood and that the rejections are based on a faulty premise. We will step back and explain the invention so as to make it clearer as to why the instant rejections are improper and must be withdrawn.

The invention is remarkable simple, yet elegant. The tool is NOT a bone or tissue harvester as in Bonutti, U.S. Patent 5,577,517 ('517). Rather, it is a tool for injecting bone replacement material into cavities **after** the bone material has been harvested. The problem to be solved in the invention was how to fill an expandable fabric bag held within a bony cavity. High distraction forces are needed in order to place bone material into such expandable bags to fill the bags as required. Simply filling using a tube is not successful as low distraction forces are created and may allow the fill tube to be blown back out of the bag opening (Pat. Appln. P.3, lines 6-9).

The solution is the inventive fill tube as claimed. It involves an elongated hollow tube with a proximal end adapted for attachment to a source of bone replacement material under pressure and a distal end including at least one deflector opening for deflecting bone out at an angle, the deflector opening having a length between about 1D to 3D, wherein D is the internal diameter of the tube. Note also that the distal end comprised a tapered tip.

In marked contrast, Bonutti teaches a flexible drill shaft with a cutting tip to cut body tissues and suction to suck the cut material into its tube.

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The Office Action cites Bonutti '517 as making the claims obvious. The Office Action refers to configuration of a cutting tip as being a mere design choice within the skill in the art. This rejection must be reversed since there is no cutting tip in the current invention. There is neither suction nor cutting in the invention as claimed. A rejection based on Bonutti which has a flexible drill with a cutting tip must be withdrawn as unsupported by law.

Reference to *Ex parte Marsham*, 2 USPQ2d 1647 (1987) is misplaced. That case discusses intended use in a claim as not being sufficient to avoid an anticipatory reference. Here, the rejection is on obviousness and the invention as claimed has clear structural differences dictated by the stated intended use. For example, the proximal end of the hollow tube in claim 1 is adapted for attachment to a source of bone replacement material under pressure. There is no deflector opening in the Bonutti reference for deflecting material distally out of the device let alone any teaching or suggestion of "design considerations" which may be required in preventing the harder pushing and packing of material within the device as noted in the application at page 4, lines 24-30.

Nothing in the cited reference provides any teaching or suggestion for the device as claimed which is designed to supply bone material to an injection site to provide considerable distraction forces outwardly. Instead, the Bonutti reference refers to, teaches and suggests various cutting heads that will allow cut material to be carried inside by suction. There is no consideration to the very different problems in directing bone material under pressure through the device to distract an expandable bag. Compaction and jamming within the flexible suction tube of Bonutti is not a concern. The Bonutti reference doesn't even appreciate the problems involved in directing bone material out of the claimed device without creating a rigid bar of bone material

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that would cause damage when injected into a body space.

Bonutti discloses a percutaneous bone *removal* apparatus 10 having a flexible shaft 14 and a cutting tip 16. The cutting tip 16 has a cutting edge 40 and an opening 38 through which tissue fragments severed by the cutting tip may be removed by suction. The tissue fragments are then carried back through the shaft 14 to eventually become trapped in a strainer 28. See Figures 1 and 3, and column 5, lines 27 – 60.

Bonutti in no way discloses or suggests using the bone removal apparatus 10 for directing bone replacement material *into* a fill space. The Examiner has provided absolutely no suggestion that the Bonutti bone removal apparatus would even be suitable for such use.

In fact, Bonutti teaches away from using the bone removal apparatus for directing material into a fill space. Bonutti discloses that tissue fragments removed using the bone removal apparatus and harvested may be used as a graft material 190. The graft material 190 may be inserted into a biodegradable sac 192, and the sac may be inserted into the bone using a cannula 180. Alternatively, loose graft material 190 may be inserted through a funnel 196 and sleeve 198 located within the cannula. See Figures 18 and 19A, and column 9, lines 26 – 66.

Thus, Bonutti teaches methods of inserting graft material other than by using the bone removal apparatus. Therefore, Bonutti teaches away from using the bone removal apparatus to insert material into a defined space.

“A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Applicants respectfully submit that independent claim 1 is not made obvious in light of Bonutti.

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Claims 3 – 6 and 12 depend from independent claim 1 and therefore also are not made obvious by Bonutti for at least the reasons discussed above. For the same reasons, claims 13 through 17 are patentable. Accordingly, Applicants respectfully request the withdrawal of the rejections under 35 USC § 103.

Lastly, it is noted that claims 7-11 have been stated to be withdrawn from prosecution as non-elected claims. In an Amendment dated September 3, 2003 Applicants noted that the Examiner had acknowledged that Claim 1 was broad enough to cover all three species. Claim 13 submitted herewith is identical to claim 1 as amended by Preliminary Amendment and is believed to be allowable. The restriction requirement should not affect claims 7-11.

Reconsideration is requested.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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By: 

Scott Q. Vidas
Registration No.: 30812

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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